

ELECTRONIC INFORMATION DISCLOSURE STATEMENT

TRADE Electronic Version v18 Stylesheet Version v18.0

> Title of Invention

METHOD FOR PREPARING SUBMICRON SUSPENSIONS WITH POLYMORPH CONTROL

Application Number:

10/035821

2470

Confirmation Number:

First Named Applicant:

Jane Werling

Attorney Docket Number: IF-5657A-1

Art Unit:

1615

Examiner:

Simon Oh

Search string:

(2745785 or 4073943 or 4540602 or 4606940 or 4608278 or 4826689 or 4997454 or 5049322 or 5118528 or 5122543 or 5151264 or 5174930 or 5269979 or 5314506 or 5318767 or 5354563 or 5417956 or 5466646 or 5474989 or 5518187 or 5560932 or 5591456 or 5605785 or 5626864 or 5635609 or 5641745 or 5665383 or 5707634 or 5720551 or 5780062 or 5862999 or 5916583 or 5939100 or 5981719 or 5989583 or 6039981 or 6045826 or 6139870 or 6207134 or 6221322 or 6221398 or 6231890 or 6306406 or 6344271 or 6346533 or 6365191 or 6375986 or 6395300 or 6428814 or 6462093 or 6607784 or RE35338

or 20010007678 or 20010025058 or

20010042932 or 20020012675 or 20020012704

or 20020041896 or 20020054912 or

20020110599 or 20020127278 or 20020168402

or 20030003155 or 20030031719 or

20030059472 or 20030072807 or 20030077329

or 20030096013 or 20030100568 or 20030206959 or 20040022862).pn.

US Patent Documents

Note: Applicant is not required to submit a paper copy of cited US Patent Documents

init	Cite.No.	Patent No.	Date	Patentee	Kind	Class	Subclass
\square) 1	2745785	1956-05-01	Bruce et al.			
	2	4073943	1978-02-14	Wretlind et al.			
	3	4540602	1982-09-10	Motoyama et al.			

7		·		
50	4	4606940	1986-08-19	Frank et al.
	5	4608278	1986-08-26	Frank et al.
	6	4826689	1989-05-02	Violanto
	7	4997454	1991-03-05	Violante et al.
	. 8	5049322	1991-09-17	Devissaguet et al.
	9	5118528	1992-06-02	Fessi et al.
	10	5122543	1992-06-16	Khanna
	11	5151264	1992-09-29	Samain et al.
	12	5174930	1992-12-29	Stainmesse et al.
	13	5269979	1993-12-14	Fountain
	14	5314506	1994-05-24	Midler, Jr. et al.
	15	5318767	1994-06-07	Liversidge
	16	5354563	1994-10-11	Toyotama
	17	5417956	1995-05-23	Moser
	18	5466646	1995-11-14	Moser
	19	5474989	1995-12-12	Hashimoto et al.
	20	5518187	1996-05-21	Bruno et al.
	21	5560932	1996-10-01	Bagchi et al.
	22	5591456	1997-01-07	Franson et al.
	23	5605785	1997-02-25	Texter et al.
	24	5626864	1997-05-06	Rosenberg et al.
	25	5635609	1997-06-03	Levy et al.
	26	5641745	1997-06-24	Ramtoola
- ′	27	5665383	1997-09-09	Grinstaff et al.
	28	5707634	1998-01-13	Schmitt
	29	5720551	1998-02-24	Shechter
	30	5780062	1998-07-14	Frank et al.
	31	5862999	1999-01-26	Czekai et al.
	32	5916583	1999-06-29	Broberg et al.
	33	5939100	1999-08-17	Albrechtsen et al.
	34	5981719	1999-11-09	Woiszwillo et al.
	35	5989583	1999-11-23	Amselem
	36	6039981	2000-03-21	Woo et al.
	37	6045826	2000-04-04	Borowy-Borowski et al.
	38	6139870	2000-10-31	Verrecchia
	39	6207134	2001-03-27	Fahlvik et al.

KA	40	6221322	2001-04-24	Thumm et al.
	41	6221398	2001-04-24	Jakupovic et al.
	42	6231890	2001-05-15	Naito et al.
	43	6306406	2001-10-23	Deluca
	44	6344271	2002-02-05	Yadav et al.
	45	6346533	2002-02-12	Cha et al.
	46	6365191	2002-04-02	Burman et al.
	47	6375986	2002-04-23	Ryde et al.
	48	6395300	2002-05-28	Straub et al.
	49	6428814	2002-08-06	Bosch et al.
	50	6462093	2002-10-08	Miyamoto et al.
	51	6607784	2003-08-19	Kipp et al.
	52	RE35338	1996-09-24	Haynes

US Published Applications

Note: Applicant is not required to submit a paper copy of cited US Published Applications

init	Cite.No.	Pub. No.	Date	Applicant	Kind	Class	Subclass
	1	20010007678	2001-07-12	Baert et al.			
	2	20010025058	2001-09-27	Borowy-Borowski et al.			
	3	20010042932	2001-11-22	Mathiowtiz et al.			
	4	20020012675	2002-01-31	Jain et al.			
	5	20020012704	2002-01-31	Pace et al.			·
	6	20020041896	2002-04-11	Straub et al.			
	7	20020054912	2002-05-09	Kim et al.			
	8	20020110599	2002-08-15	Auweter et al.			
	9	20020127278	2002-09-12	Kipp et al.			
	10	20020168402	2002-11-14	Kipp et al.			
	11	20030003155	2003-01-02	Kipp et al.			
	12	20030031719	2003-02-13	Kipp et al.			
	13	20030059472	2003-03-27	Brynjelsen et al.			
	14	20030072807	2003-04-17	Wong et al.			
	15	20030077329	2003-04-24	Kipp et al.			
	16	20030096013	2003-05-22	Werling et al.			
	17	20030100568	2003-05-29	Werling et al.			
	18	20030206959	2003-11-06	Kipp et al.	A9		
	•						

19 20040022862 2004-02-05	Kipp et al.
Signature	
Examiner Name	, Date
Sinor Or	12/2/04

OIPE

MAY 1 0 2004

INFORMATION DISCLOSURE CITATION IN AN APPLICATION

(use several sheets if necessary)

DANA	**	
PIO	Form	144

Atty Docket No. IFT-5657A-1	Application No. 10/035,821			
Applicant Werling et al.				
Filing Date	Group			
Oct. 19, 2001	1615			

	U.S. PA	TENT DOCUMEN	ΓS		
Document Number	Publication Date	Inventor	Class	Subclass	Filing Date If Appropriate
					
<u></u>					
		, , , , , , , , , , , , , , , , , , , 			
					· · · · · · · · · · · · · · · · · · ·
		Document Publication	Document Publication Number Date Inventor	Document Number Publication Date Inventor Class	Document Number Publication Date Inventor Class Subclass

Examiner's		Document	Publication				Trans	lation
Initials		Number	Date	Country	Class	Subclass	Yes	No
	51)	EP 0169 618 B2	10 Nov 1993	EP			X	
	7	EP 0207 134 B1	17 Aug 1994	EP			X	
		EP 0275 796 B2	6 Sept 1995	EP	***************************************			X
		EP 0349 428 B1	20 Jan 1993	EP			X	
		EP 0372 070 B1	15 Jan 1997	EP			X	
		EP 0377 477 B1	24 Mar 1993	EP			X	
		EP 0379 379 B1	18 Jan 1990	EP			X	
		EP 0498 482 B1	8 Sept 1999	EP			X	
	1.	EP 0499 299 B1	16 Aug 2000	EP			X	
		EP 0517 565 B1	18 Oct 2000	EP			X	
		EP 0535 534 A1	7 Apr 1993	EP			X	
	7	EP 0577 215 A1	1 May 1994	EP		· · · · · · · · · · · · · · · · · · ·	X	
		EP 0600 532 A2	8 June 1994	EP			X	
		EP 0600 532 A3						
		EP 0601 618 A2	15 June 1994	EP			X	
		EP 0601 618 A3						
		EP 0601 619 A2	15 June 1994	EP	P		X	
		EP 0601 619 A3				1		I

^{*}Examiner: Initial if citation considered whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION IN AN APPLICATION (use several sheets if necessary)

Atty Docket No. IFT-5657A-1	Application No. 10/035,821
Applicant Werling et al.	·
Filing Date Oct. 19, 2001	Group 1615

PTO Form 1449

		FOREIGN PA	TENT DOCUM	ENTS				
Examiner's	Document	Publication					Trans	ation
Initials	Number	Date	Country	Clas	ss	Subclass	Yes	No
80	EP 0602 700 A2	22 June 1994	EP				X	
	EP 0602 700 A3	22 1 1004	rn				X	
	EP 0602 702 A1	22 June 1994	EP					
	EP 0605 024 A2 EP 0605 024 A3	6 July 1994	EP				X	
	EP 0644 755 B1	19 Mar 1997	EP				X	
	EP 0720 471 B1	18 Apr 2001	EP				X	
	EP 0730 406 B1	8 July 1998	EP				X	
	EP 0752 245 B1	22 May 2002	EP				X	
	EP 0754 034 B1	22 Jan 1997	EP		i		X	22
	EP 0788 350 B1	27 Feb 2002	EP			· · · · · · · · · · · · · · · · · · ·	X	
	EP 0804 162 B1	5 Sept 2001	EP				X	
	EP 0808 154 B1	20 Dec 2000	EP				X	
	EP 0812 187 B1	2 May 2003	EP				X	
	EP 0820 300 B1	2 Apr. 1996	EP				X	
	EP 0828 479 B1	24 Oct 2001	EP				X	
	EP 0831 770 B1	16 Aug 2000	EP				X	
,	EP 0832 569 A2	1 Apr 1998	EP				X	
	EP 0832 569 B1	26 Nov 2003						
	EP 0988 863 A3	9 Aug 2000	EP				X	
	EP 1012 204 B1	29 Jan 2003	EP				X	
	EP 1105 109 B1	23 Apr 2003	EP				X	
	EP 1156 788 B1	15 Jan 2003	EP				X	
	EP 1210 942 A2	5 June 2002	EP				X	
	WØ 85/00011 A1	3 Jan 1985	WODET	· [X	
	WO 86/03676 A1	3 July 1986	WO PCT				X	
	89/11850 A1 فهلا	14 Dec 1989	Wo Pet				X	
	WO 90/03782 A2	19 Apr 1990	WO PET				X	
	WO 90/15593 A1	27 Dec 1990	WO BET			·	X	
	WO 91/06292 A1	16 May 1991	WOPCF				X	
	WØ 91/12794 A1	5 Sept 1991	WOPET				X	
	₩Ó 91/16068 A1	31 Oct 1991	WOPET				X	
	₩Ó 92/00731 A1	23 Jan 1992	WO PET				X	
	₩Ó 92/03380 A1	5 Mar 1992	WO PET				X	
	WO 93/25190 A1	23 Dec 1993	WO PET	:			X	
/	W-94/20072 A1	15 Sept 1994	WO BEF				X	
Y	₩O 95/05164 A1	23 Feb 1995	WO PET			/ //	X	
Examiner:	Simo (Lh	Date Co	onsidered:	47	12/04	1	

*Examiner: Initial if citation considered whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION IN AN APPLICATION

(use several sheets if necessary)

Atty Docket No.	Application No.
IFT-5657A-1	10/035,821
Applicant Werling et al.	
Filing Date	Group
Oct. 19, 2001	1615

PTO Form 1449

		FOREIGN PAT	TENT DOCUMENT	S			
Examiner's	Document	Publication				Trans	lation
Initials	Number	Date	Country	Class	Subclass	Yes	No
30)	WO 95/27482 A1	19 Oct 1995	PET WO			X	
	WO 96/00567 A1	11 Jan 1996	PET WO			X	
	WO 96/14833 A1	23 May 1996	PET WO			X	
	WO 96/20698 A2	11 July 1996	PCT WO			X	
	WO 96/24336 A1	15 Aug 1996	PET WO			X	·
	WO 96/24340 A1	15 Aug 1996	PET WO			X	
	ЖО 96/25150 A1	22 Aug 1996	PCT WO			X	
	WO 96/25152 A1	22 Aug 1996	PCF WO			X	
	₩O 96/25918 A1	28 Aug 1996	PCF NO			X	
	₩0 96/31231 A1	10 Oct 1996	PET NO			X	
	₩O 97/03657 A1	19 July 1996	PCT WO			X	
	WØ 97/14407 A1	24 Apr 1997	PCT WO			X	
	WO 97/30695 A1	28 Aug 1997	PCT WO			X	
	WO 97/36611 A1	9 Oct 1997	PCT WO			X	
	WO 97/41837 A2	13 Nov 1997	PET WO			X	
	WO 97/44014 A1	27 Nov 1997	PCT WO			X	
	WO 98/07410 A1	26 Feb 1998	PET WO			X	
	WO 98/07414 A1	26 Feb 1998	PET Wo			Х	
,	WO 98/14174 A1.	9 Apr 1998	PCT WO			X	
	₩O 98/14180 A1	9 Apr 1998	PCT WO			X	
	₩ O 98/35666 A1	20 Aug 1998	PCT WO			X	
	₩O 98/57967 A1	23 Dec 1998	PET WO			Х	
1	WO 99/00113 A1	7 Jan 1999	PCT WO			X	
	₩O 99/02665 A1	21 Jan 1999	DET WO			X	
	WO 99/03450 A1	29 Jan 1999	DET WI			X	
	WO 99/16443 A1	8 Apr 1999	PET WO			X	
γ.	УЮ 99/29316 A1	17 June 1999	PET WO			X	
	₩Ð 99/30833 A1	24 June 1999	PCT-WO			X	
	₩O 99/32156 A2	1 July 1999	DET WO			X	
	WO 99/33467 A1	8 July 1999	PCP WO			X	
	₩O 99/38493 A1	5 Aug 1999	POT WO			X	
	₩O 99/49846 A2	7 Oct 1999	PET WO			X	
	WO 99/49848 A1	7 Oct 1999	PET WO			X	
	ЖÓ 99/61001 A1	2 Dec 1999	PCT WO			X	
	жб 99/65469 A3	23 Dec 1999	PET WO	V		X	

Examiner: Surve Ch Date Considered: \$7/2/04

^{*}Examiner: Initial if citation considered whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IN AN APPLICATION (use several sheets if necessary)

PTO Form 1449

Atty Docket No. IFT-5657A-1	Application No. 10/035,821		
Applicant Werling et al.			
Filing Date Oct. 19, 2001	Group 1615		

Examiner's	Document	FOREIGN PATENT DOCUMENTS Publication		Translation			
Initials	Number	Date	Country	Class	Subclass	Yes	No
40	WC 00/09096 B1	24 Feb 2000	WOPET			X	
7	₩O 00/12124 A1	9 Mar 2000	POT		· ·	X	
	WO 00/12125 A1	9 Mar 2000	PET			X	
	WO 00/18374 A1	6 Apr 2000	PET			X	
	WO 00/27363 A1	18 May 2000	PeT			X	
	WO 00/30615 A1	2 June 2000	PCT			X	
	. WO 00/30616 A1	2 June 2000	PET			X	
	₩O 00/37050 A1	29 June 2000	Pet			X	
	₩O 00/40220 A1	13 July 2000	PCP			X	
	₩O 00/51572 B1	8 Sept 2000	Per			X	
	WO 00/71079 A2	30 Nov 2000	PCT			X	
	WO 01/12155 A1	22 Feb 2001	PCT	1		X	
	₩O 01/17546 A1	15 Mar 2001	PCP			X	
	WO 01/26635 A2	19 Apr 2001	PCT			X	
	WO 01/62374 A2	30 Aug 2001	Pet			X	
	₩O 01/64164 A2	7 Sept 2001	PGT			X	
	₩O 01/80828 A2	1 Nov 2001	.PeT			X	
	WO 01/85345 A1	15 Nov 2001	PET			X	
	₩O 01/87264 A2	22 Nov 2001	PCT			X	
	₩O 02/17883 A2	7 Mar 2002	PET			X	
	WO 02/24169 A1	28 Mar 2002	PCT			X	
	WO 02/24163 A1	28 Mar 2002	PET			Х	
	WO 02/43702 A2	6 June 2002	PCT			X	
	WO 02/51386 A2	7 July 2002	PET			X	
	₩O 02/55059 A2	18 July 2002	PCT			X	
	WO 02/60411 A2	8 Aug 2002	PET			X	
	₩ 0 -02/72070 A1	19 Sept 2002	PGT			X	-
	WO 02/72071 A1	19 Sept 2002	PCT-			X	
	WO -02/74282 A1	26 Sept 2002	PCT			X	
	- WO 02/80883 A2	17 Oct 2002	PCT			X	
	₩O 02/89773 A2	14 Nov 2002	PCT			X	
	WO 03/26611 A2 WO 03/26611 A3	3 Apr 2003	PET			Х	
	WO 03/35031 A1	1 May 2003	WOPET	 		Х	·

Examiner: Sww ()	Date Considered: (2/	2/04
*Examiner: Initial if citation considered whether or not cital line through citation if not in conformance and not communication to applicant.		



INFORMATION DISCLOSURE CITATION IN AN APPLICATION (use several sheets if necessary)

PTO Form 1449

Atty Docket No. IFT-5657A-1	Application No. 10/035,821		
Applicant Werling et al.			
Filing Date Oct. 19, 2001	Group 1615		

Examiner's Initials		OTHER DOCUMENTS (Including Author Title Date Pertinent Pages Etc.)
50		Davis et al., "Pulmonary Perfusion Imaging: Acute Toxicity and Safety Factors as a Function of Particle Size", J.Nucl Med., Vol. 19 (1978), pp. 1209-1213.
		Schroeder et al., "Physiological Effects of Subvisible Microspheres Administered Intravenously to Beagle Dogs", Journal of Pharmaceutical Sciences, Vol. 67, No. 4, April 1978, pp. 508-512.
	-	Yokel et al., "Acute Toxicity of Latex Microspheres", Toxicity Letters, Vol. 9 (1981), pp. 165-170.
		Allen et al., "Critical Evaluation of Acute Cardiopulminary Toxicity of Microspheres", J.Nucl Med., Vol. 19 (1987), pp. 1204-1208.
	: .	B. Sjostrom et al., "Preparation Of Submicron Drug Particles In Lecithin-Stabilized O/W Emulsions I. Model Studies Of The Precipitation Of Cholesteryl Acetate", Int. J. Pharm., 88 (1992) pp 53-62.
		B. Sjostrom et al., "A Method For The Preparation Of Submicron Particles Of Sparingly Water-Soluble Drugs By Precipitation In Oil-In-Water Emulsions. II: Influence Of The Emulsifier, The Solvent And The Drug Substance", J. Pharm. Sci., 82(6), (1992) pp 584-589.
		Duncker and Reichelt, "Effects of the Pharmaceutical Cosolvent hydroxypropyl-beta- cyclodextrin on Porcine Corneal Endothelium", Graefe's Archive for Clinical and Experimental Ophthalmology (Germany), 236/5 (1998), pp. 380-389.
		Volchek and Dellen, "Anaphylaxis to Intravenous Cyclosporine and Tolerance to Oral Cyclosporine, Case Report and Review", Annals of Allergy, Asthma, and Immunology, 80 (1998), pp. 159-163.
		Singla et al., "Paclitaxel and its Formulations", International Journal of Pharmaceutics, 235/1-2 (2002), pp. 179-192.
		B. Sjostrom et al., "The Formation of Submicron Organic Particles by Precipitation in an Emulsion", J.Dispersion Science and Technology, 15(1), 89-117 (1994).
		Avanti Polar Lipids, Inc, website printout, www.avantilipids.com, "Synthetic Products – Functionalized Phospholipids: Lipids for Conjugation of Proteins/Peptides/Drugs to Liposomes" (7 pgs), March 2003.
		Avanti Polar Lipids, Inc, website printout, www.avantilipids.com, "Polymer and Polymerizable Lipids: Functionalized PEG Lipids" (3 pgs), March 2003.
		Avanti Polar Lipids, Inc, website printout, www.avantilipids.com, "Polymer and Polymerizable Lipids: Poly(ethylene glycol)-Lipid Conjugates" (8 pgs), March 2003.
	·	

			<u>/</u>
Examiner: Limin ()	Date Considered: 12	102/	04
*Examiner: Initial if citation considered whether or not cita	ation is in conformance with N	MPEP Section	on 609; Draw
line through citation if not in conformance and not	considered. Include copy of	of this form	n with next
communication to applicant.			